DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT
M4024V1

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106

Telephone: 215-597-4390

WARNING LETTER

August 4, 2000

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

John R. Wigle, Owner
RD #2
P.O. Box 348
Latrobe, PA 15650

Dear Mr. Wigle:

On June 27, 2000 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your dairy farm in response to United States Department of Agriculture (USDA) reports regarding violative drug residues in two (2) cows you offered for slaughter for human food in August 1999. Additional investigation by the FDA at [redacted] and [redacted], your veterinarian, revealed serious violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our inspection determined that on or about August 16, 1999 you provided a cow, back tag [redacted], to Gontis Livestock for delivery for human food without informing the firm regarding the medication status of the animal. Similarly, on or about August 25, 1999 you delivered a cow, back tag, [redacted] to [redacted] for sale for slaughter for human food without informing the firm of the medication status of this animal. As a result both cows were slaughtered for human food at [redacted] and upon USDA testing, revealed violative gentamicin residues in their kidney tissue as follows:

Back Tag	Slaughter Date	Slaughterhouse	Residue (ppm) Kidney Tissue	Tolerance (ppm)
[redacted]	8/16/99	[redacted]	Gentamicin: 1.50	0
[redacted]	8/27/99	[redacted]	Gentamicin: 5.20	0

Gentamicin is not approved for oral or injectable use in cattle, and therefore, there is no tolerance for the presence of this drug in edible bovine tissue. The presence of gentamicin in the edible tissues from your animals renders the food from the animals adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system to assure that animals have been treated with drugs which have been approved for use in those species, that drugs are not used in a manner contrary to the directions contained in the labeling, and that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

Our inspection determined that you had no records regarding the medication of the referenced cows nor did you have any records regarding the period of time you withheld the cows from slaughter after treatment with gentamicin. Additionally, you admitted that you did not perform a urine test prior to shipping the cows for slaughter for human food, as directed by your veterinarian on the product label.

The FDA is also aware of another medicated cow, back tag [redacted] which you offered for slaughter for human food at [redacted] The cow was slaughtered on or about June 4, 1999 and subsequent USDA testing revealed 5.60 ppm gentamicin in its kidney tissue.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing

the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violation and prevent its recurrence.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely,

Margaret E Eagen

for Thomas D. Gardine
District Director
Philadelphia District

jci

cc: Dr. John I. Enck, Director
PA Department of Agriculture
Bureau of Animal Health and Diagnostic Services (BAHDS)
2301 North Cameron Street
Harrisburg, PA 17120

cc: Food Safety and Inspection Service (FSIS)
106 South 15th Street
Suite 904
Omaha, Nebraska 68102
Attention: Residue Staff